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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,230	03/16/2004	Timothy P. Herbert	P-11749.00	2020

27581 7590 01/23/2006

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EXAMINER	
PATEL, JOY	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 01/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/801,230	HERBERT ET AL.	
	Examiner	Art Unit	
	Joy P. Patel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,12,14-27,29,31-44,47 and 49-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-8,12,14-16,18-27,29,31-44,47 and 49-56* is/are rejected.

7)☒ Claim(s) *17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 November 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-6, 14-16, 20-22, 24-26, 31, 32, 35-37, 39-42, 49, 51, 52, 55, and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Colliou et al. (US 2004/0243211).

2. In regard to claims 1 and 39, Colliou discloses, "A device, system and method for diagnosing and treating a patient is provided where a functional device is attached to a stomach wall. The device in one embodiment provides electrical stimulation of the stomach wall" (Abstract, lines 1-4). The stomach is known to be a part of the gastrointestinal tract. Colliou further discloses, "The stimulation electrodes provide stimulation either by way of a preprogrammed pulse generator or one that is programmed or revised when the device is implanted in the stomach, e.g. based on sensed parameters or response to stimulation and/or to optimize various parameters, e.g., impedance, current density, etc." (Paragraph 16, lines 1-6). In regard to the battery, Colliou discloses, "The stimulator device

may be powered by a battery included with the device or may be inductively powered, e.g. by an external source" (Paragraph 19, lines 4-6). In regard to the fixation structure, Colliou discloses, "The device includes a chamber for receiving tissue of the stomach wall for attachment where a vacuum pressure is applied through the chamber to draw the tissue into the chamber" (Abstract, lines 15-18; See also Figure 1). Since the claim states than any of three various forms of attachment mechanisms (an expandable frame, a cavity within the housing, or barbed hooks) can be implemented to attach the device to the gastrointestinal tract, the device of Colliou discloses the use of a cavity within the housing as a means of attachment.

3. In regard to claims 2, 3, and 5 see figure 1.

4. In regard to claims 4 and 41, Colliou discloses, Colliou discloses, "The device includes a chamber for receiving tissue of the stomach wall for attachment where a vacuum pressure is applied through the chamber to draw the tissue into the chamber" (Abstract, lines 15-18; See also Figure 1).

5. In regard to claim 6, Colliou discloses, "The device includes a chamber for receiving tissue of the stomach wall for attachment where a vacuum pressure is applied through the chamber to draw the tissue into the chamber" (Abstract, lines 15-18; See also Figure 1)". Although the applicant claims "two or more cavities and vacuum ports", the MPEP states, "Although the reference did not disclose a plurality of ribs, the court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced" (MPEP, 2144.04

VI, B). In this instance, no new or unexpected result is produced; one vacuum port performs the same function as two vacuum ports (to suck in tissue so that the anchor needles can be placed through the tissue.

6. In regard to claims 14, 31, and 49, Colliou discloses, "The devices are thin in one dimension so that they are less visible when implanted directly under the skin or muscle layer. Therefore, in order to accommodate the necessary battery capacity, the devices are widely shaped, e.g. round or kidney shaped in the other two dimensions" (Paragraph 8, lines 7-14). A shape that is flat (or thin) in one dimension and widely shaped (round or kidney shaped in the other two dimensions (length and width)) is known to resemble a disc-like shape.

7. In regard to claims 15, 32, and 42, Colliou discloses, "Each anchor needle includes one or more electrodes, which are connected to the electronics and battery" (Paragraph 22, lines 3-5; See also figure 1).

8. In regard to claim 16, Colliou discloses, "The electrodes may be mounted directly on the housing, the attachment device, or placed on a flexible tail or tether" (Paragraph 27, lines 1-3).

9. In regard to claims 24 and 40, Colliou discloses, "As illustrated in FIG. 17, to implant the device in the stomach, an endoscope 110 is used with various instruments as will be described in more detail below. A flexible endoscope 110 is used to locate an implantation site 105 within the stomach 100 and implant the stimulator device...at site 105 within the stomach wall 104 of a patient" (Paragraph 89, lines 1-8; See also figure 17).

10. In regard to claims 20, 21, 25, 35, 36, 51, 52, 55, and 56, Colliou discloses, "Electrical stimulation of the gastrointestinal tract has been proposed to treat motility related disorders and other gastrointestinal diseases or conditions. The electrical stimulation has been proposed in a number of forms, such as, e.g., pacing, electrical contractile stimulation or other stimulation, e.g., to treat nausea or obesity" (Paragraph 4, lines 1-6). Nausea is a known symptom of gastroparesis chemotherapy, post-operative ileus, functional dyspepsia, and pregnancy. (In specific regard to claim 25, see also rejection for claim 1).

11. In regard to claims 22, 37, and 53, Colliou discloses, "Fig. 16B illustrates an alternate waveform design for stimulating the stomach wall. The waveform 502 utilizes bursts of pulses rather than a single pulse. The burst repetition rate is selected, preferably, to between about 2 to 12 cycles per minute (this corresponds to a burst repetition period of between 5 to 30 seconds). The duration of a pulse in this example is between about 100 microseconds and 20ms, and has amplitude of about 1-30mA. The frequency of the burst pulses during a burst period is about 50Hz to 10KHz corresponding to a pulse repetition period of 100 microseconds to 20 ms. The burst duration can vary from about 0.1ms to 1 second" (Paragraph 140, lines 9-21). Here the "duration of a pulse" is the pulse width and the "burst duration" is the on duty cycle. Furthermore, the off duty cycle is defined by the burst repetition rate which is between 2 to 12 cycles per minute, which means that the off duty cycle varies from 5 to 30 seconds. The

value ranges provided in claims 22, 23, 37, 38, 53, and 54 are anticipated by the disclosure of Colliou et al.

12. In regard to claim 26, see figure 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims18, 23, 33, 38, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colliou et al. (US 2004/0243211).

14. In regard to claims 18 and 33, Colliou, as discussed above, discloses an implantable gastrointestinal stimulation device. Since the device of Colliou treats the same regions as the device of the applicant, it would have been obvious to one of ordinary skill in the art to create an implantable gastrointestinal stimulator of a similar size.

15. In regard to claims 23, 38, and 54, it is well known in the art that waveforms of various frequencies and amplitudes are necessary to treat various gastrointestinal disorders. Therefore, it would have been obvious to one of

ordinary skill in the art to set the pulse generator to produce a waveform with an amplitude of approximately 5mA, a frequency of approximately 14Hz, a pulse width of approximately 330 microseconds, an on duty cycle of approximately 0.1 seconds, with an off duty cycle of approximately 5 seconds in order to achieve the desired results.

16. Claims 7, 8 27, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colliou et al. (US 2004/0243211) in view of Kilcoyne et al. (US 2005/0043601).

17. In regard to claims 7, 27, and 43, Colliou, as discussed above, discloses an implantable gastrointestinal stimulation device, which incorporates a vacuum port and anchoring needles in order to attach the device into the patient's stomach wall. However, Colliou fails to disclose the use of other attachment means, such as barbed hooks. Kilcoyne (US 2005/0043601), on the other hand, discloses an implantable device that can be attached to the esophagus (which is a part of the gastrointestinal tract) and incorporates a vacuum port, anchoring needles, as well as hooks. Kilcoyne discloses, "In further embodiments of the present method, the monitor 18 is attached to the esophagus 30 using one or more sutures, clips, staples, tacks, pins, hooks, barbs, or other securing structures that can penetrate the mucosa of the esophagus" (Paragraph 87, lines 1-5). It would have been obvious to one of ordinary skill in the art to modify the device of Colliou in view of

the teachings of Kilcoyne in order to provide further attachment means to the device to securely hold it in place, as the Kilcoyne device demonstrates.

18. In regard to claims 8 and 44, Colliou, as discussed above, discloses an implantable gastrointestinal stimulation device, which incorporates a vacuum port and anchoring needles (with electrodes) in order to attach the device into the patient's stomach wall. However, Colliou fails to disclose the use of other attachment means, such as barbed hooks. Kilcoyne discloses, "In further embodiments of the present method, the monitor 18 is attached to the esophagus 30 using one or more sutures, clips, staples, tacks, pins, hooks, barbs, or other securing structures that can penetrate the mucosa of the esophagus" (Paragraph 87, lines 1-5). It would have been obvious to one of ordinary skill in the art to modify the device of Colliou in view of the teachings of Kilcoyne to have barbed hooks with hooks in order to provide further attachment means to the device to securely hold it in place and to use the attachment means as a means to sense physiologic signals as the anchoring needles currently do.

19. Claims 12, 29, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colliou et al (US 2004/0243211) in view of Imran (2005/0090873).

20. In regard to claims 12, 29, and 47, Colliou, as discussed above, teaches an implantable gastrointestinal stimulation device, which incorporates a vacuum port and anchoring needles in order to attach the device into the patient's stomach

wall. Imran, on the other hand, teaches a gastrointestinal stimulation device that is composed of "A fixation device for holding stimulating electrodes in electrical contact with the wall of a portion of the gastrointestinal tract" (Abstract lines 1-3). Imran further teaches, "According to another embodiment of the invention, the fixation device comprises a self-expanding tubular member." (Paragraph 7, lines 10-12) (See also figures 1A and 1B). The primary difference between these two references is that Colliou implements an anchoring mechanism which requires the gastrointestinal wall to be punctured, while the anchoring mechanism presented by Imran does not require the wall to be punctured. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Colliou in view of the teachings of Imran in order to create an implantable gastrointestinal stimulation device which would not require the gastrointestinal wall to be punctured and therefore be less invasive to the patient.

21. Claims 19 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colliou et al. (US 2004/0243211) in view of Swoyer et al. (US 6,754,536).

22. In regard to claims 19 and 34, Colliou, as discussed above, teaches an implantable gastrointestinal stimulation device, which incorporates a vacuum port and anchoring needles in order to attach the device into the patient's stomach wall. However, Colliou fails to teach that the anchoring needles are degradable and can be implemented for temporary use. Swoyer, on the other hand, teaches attachment mechanisms that are degradable. Swoyer discloses, "For temporary

use, the fixation mechanism can be made of a material that is degraded by stomach acid over time to release the GI tract stimulator or monitor IMD and allow it to pass through the GI tract (Column 6, lines 23-26). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Colliou so that it could be implanted for temporary use and simply pass through the GI tract after it had provided the necessary treatment to the patient.

Allowable Subject Matter

23. Claim 17 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Amendment

24. The amendment filed on November 29, 2005 under 37 CFR 1.131 is sufficient to overcome the Swoyer (US 6,754,536) and Imran (US 2004/0088023) references. However, a new basis for rejection has been applied and the amendment is moot. Therefore, the rejection is final.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joy P. Patel whose telephone number is 571-272-5556. The examiner can normally be reached on Monday-Friday 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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